510(k) Summary

K 121462

Submitted by: EZ-Blocker B.V.
Delftechpark 26
Delft 2628 XH
The Netherlands

SEP 28 2012

Contact Person: Lewis Ward
L.W. Ward and Associates, Inc.
4655 Kirkwood Court
Boulder, CO 80301
303-530-3279

Date Prepared: 9-14-2012

Product: EZ-Blocker

Classification Name: Tracheal/bronchial differential ventilation tube, Product Code CBI Regulation Number 868.5740

Intended Use: The EZ-Blocker is indicated for use to intubate the patient's bronchi in order to differentially isolate the left or right lung for procedures which require one-lung ventilation, lung separation.

Technological Characteristics:

The EZ-Blocker is a double lumen endobronchial tube made of polymer materials and inks. The distal part of the tube ends in a "y" shape with distal extensions for each branch of the lung. The extensions are symmetrical and colored differently (blue and yellow) for identification purposes. The device is supplied with an adapter for connection to a ventilator device. The symmetrical design facilitates introduction and positioning of the device in both main stem bronchi. When properly positioned, the cuff in the main stem branches of the non-ventilated lung can be inflated and lung isolation is achieved.

Substantial Equivalence:

Feature	Cook Inc. Endobronchial Blocker, K021920	EZ-Blocker® This submission
Indication for Use	The 7.0 Fr. Endobronchial Blocker is intended for use to differentially intubate a patient's bronchus in order to isolate the left or right lung for procedures which require one-lung ventilation.	The EZ-Blocker is indicated for use to intubate the patient's bronchi in order to differentially isolate the left or right lung for procedures which require one-lung ventilation, lung separation.
Company	Cook Inc.	EZ-Blocker B.V.
Distal Tip	Single	Double
Average Inflation Volume Range	2.0 cc – 12.0 cc	Max 12.0 cc (recommended)
Balloon	Low-pressure, high-volume Spherical or Elliptical	Low-pressure, high-volume
Lengths	50, 65, 78 cm	Tubing 69 cm Overall length 75 cm
Materials	Unknown	Silicone, Polyurethane
Biocompatibility	Performed but not specified	Cytotoxicity, Sensitization, Irritation - PASS
Testing for verifying characteristics of the cuff	- Analysis of cuff pressure at various inflation volumes - Analysis of balloon cuff inflation retention	CMI performed Balloon Verification Test No. ECO-00967-002 consisting of: checking of resting diameter, leakage, collapsing of balloon, and burst test.
Gas Barrier property	Unknown	CMI has verified by testing that the balloon retains gas without significant changes in volume up to 6 hours after inflation.
Packaging	Pouch	Pouch
Shelf Life	Unknown	2 years expiration dated

Test Data:

The EZ-Blocker has been tested and confirmed safe under ISO 10993-1 biocompatibility requirements. The assembly is validated for function, leakage, and bond strength. The device is confirmed safe and effective as a device used in standard medical practice.

The EZ-Blocker is substantially equivalent to the Cook Inc. Endobronchial Blocker K021920 based on the performance data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

EZ-Blocker B.V.
C/O Mr. Lewis Ward
President
L.W. Ward And Associates, Incorporated
4655 Kirkwood Court
Boulder, Colorado 80301

SEP 28 2012

Re: K121462
Trade/Device Name: EZ-Blocker®
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: II
Product Code: CBI
Dated: September 14, 2012
Received: September 17, 2012

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: EZ-Blocker®

Indications for Use:

The EZ-Blocker is indicated for use to intubate the patient's bronchi in order to differentially isolate the left or right lung for procedures which require one-lung ventilation, lung separation. Patient population: Patients requiring one lung isolation. Environment of use: Hospitals – OR and ICU.

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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